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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,498	07/05/2001	Cynthia L. Bristow	F.11136	2583

7590 06/19/2003

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EXAMINER

SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 06/19/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

899,498

Applicant(s)

BRISTOW

Examiner

SAUNDERS

Group Art Unit

1684

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 3/31/03
- ☒ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 9-16 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 9-16 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

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The amendment of 3/28/03 (Paper 4) has been entered. Claims 9-16 are pending and under examination.

The amendment has overcome 112 issues of record, except for the further herein below 112, first paragraph, description rejection.

New issues raised by presentation of the amendment are as follows.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Markush group of claim 16 is confusing. The first member “a fluorescent material discernable within the visible spectra” is confusing, because one does not know whether this is a fluorescent or a visible reporter. Since the second member recites “such a fluorescent material”, one likewise has no idea whether this is a fluorescent or a visible reporter.

It is also unclear as to how many members there are. The claim lists four, but it appears that the claim has been punctuated for only three. Is “4)” in the last line intended?

Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 16 contains new matter because the first member “a fluorescent materials discernable within the visible spectra” was not recited in the original disclosure.

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It appears that a “fluorescent material” and a material discernable within the visible spectrum” maybe intended as separate members in original claim 7, to the extent that claim 7 can be comprehended.

Claims 9-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has not adequately described the genus of diseases/pathologic phenomena that correlate with surface density of Human Elastase (HLE) associated with the plasma membrane of lymphocytes and phagocytes (see previous action at pages 6-7).

Applicant addressed this issue (Paper 5, pages 6-7) as a 112, scope of enablement, rather than description rejection. Whether applicant is addressing the issue of enablement or the issue of description, however, makes no difference. In either case applicant’s arguments filed 3/28/03 are unconvincing.

Applicant has urged that his invention is not directed to monitoring any disease but only to those that show the recited correlation. The problem is that this recitation of the correlation is merely a recitation of a sub genus of diseases yet to be mapped out. Under description one does not know what these are, other than AIDS and ARC. Under scope of enablement, the specification does not adequately direct one to the diseases of this recited subgenus, but, instead, merely directs one to a laundry list of diseases falling into broad categories.

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Under description, AIDS and ARC are not considered representative of the subgenus of diseases; and, under scope of enablement the exemplification of AIDS and ARC do not give one of skill any hint of what other diseases to consider.

The reason for the examiner's position that AIDS and ARC are not representative of the subgenus and are not enabling as for directing one to other diseases is that applicant has admitted (specification page 1) that HLE is known to be co-localized with CD4 on the plasma membrane. Since AIDS and ARC are related to infection by HIV, which itself attacks cells by binding to the CD4 receptor, applicant has exemplified disease/pathological states which one would reasonably expect to show the recited correlation. However, where would one go beyond these diseases to practice the claimed method? What other agents of disease bind to CD4? Applicant's claims thus leave it for others to conduct further research to find out what other members are representative of the genus and to be enabled to conduct the method beyond the monitoring of AIDS/ARC.

Since applicant has addressed the rejection of record as one of scope of enablement, the examiner deems it proper to alternatively state the following 112, scope of enablement rejection and render this Office action as final.

Claims 9-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for monitoring diseases/pathological states that are AIDS or ARC, does not reasonably provide enablement for monitoring diseases/pathological states that are merely described as correlated "with surface density of Human leukocyte Elastase". The specification

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does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. As noted supra, the disclosure has left it to others to determine, by further research, what diseases, other than AIDS or ARC, may be monitored.

Claims remain allowable over the prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunder:jmr

June 17, 2003

David A Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182-1644